GEORGIA INSTITUTE OF TECHNOLOGY OFFICE OF CONTRACT ADMINISTRATION

PROJECT ADMINISTRATION DATA SHEET

[X] ORIGINAL [ ] REVISION NO. ______

Project No. A-3607 GTRI/~~GIT~~ DATE 8 /2 /83

Project Director: Dr. Billy Livesay ~~School~~/Lab EML

Sponsor: Cilco, Inc.

Type Agreement: P.O. No. 83-2664

Award Period: From 7/1/83 To 9/30/83 (Performance) ______ (Reports)

Sponsor Amount:

	This Change	Total to Date
Estimated:	$	$
Funded:	$ 5,000	$ 5,000

Cost Sharing Amount: $ -- Cost Sharing No: --

Title: "Mechanical Fatigue Studies of Intraocular Lens Materials"

ADMINISTRATIVE DATA

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Defense Priority Rating: N/A

Military Security Classification: N/A

(or) Company/Industrial Proprietary: ______

RESTRICTIONS

See Attached -- Supplemental Information Sheet for Additional Requirements.

Travel: Foreign travel must have prior approval – Contact OCA in each case. Domestic travel requires sponsor approval where total will exceed greater of $500 or 125% of approved proposal budget category.

Equipment: Title vests with N/A; none proposed

COMMENTS:

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EORGIA INSTITUTE OF TECHNOLOGY OFFICE OF CONTRACT ADMINISTRATION

SPONSORED PROJECT TERMINATION/CLOSEOUT SHEET

Date 1/30/84

oject No. A-3607 ~~School~~/Lab EML

cludes Subproject No.(s)

oject Director(s) Dr. Billy Livesay GTRI / ~~GIT~~

ponsor Cilco, Inc.

itle "Mechanical Fatigue Studies of Intraocular Lens Materials"

ffective Completion Date: 9/30/83 (Performance) 9/30/83 (Reports)

rant/Contract Closeout Actions Remaining:

- [ ] None
- [x] Final Invoice ~~or Final Fiscal Report~~
- [ ] Closing Documents
- [ ] Final Report of Inventions
- [ ] Gov
- [ ] Class
- [ ] Other

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A-3607

INTRAOCULAR LENS LOOP

FATIGUE BEHAVIOR

Prepared For

CILCO, INC
Huntington, WV 25717

FINAL REPORT

Project No. A-3607

BY
J. W. LARSEN AND B. R. LIVESAY

January, 1984

GEORGIA INSTITUTE OF TECHNOLOGY
ATLANTA, GEORGIA USA 30332

Intraocular Lens Loop Fatigue Behavior

Introduction

This report describes the results of mechanical property fatigue tests conducted on several specimens of intraocular lenses from four different manufacturers. The work was performed under contract A-3607-000 in the Micromechanics Laboratory, EML/EES of Georgia Institute of Technology, for Cilco, Inc. The purpose of this work as stated by Cilco was "to compare the physical response of intraocular lenses with polymethylmethacrylate (PMMA) and polypropylene loops to repetitive compression".

The procedure was to monitor various physical parameters of the lenses at several stages of the compressive fatigue cycling. The physical properties to be measured were:

1) Effective diameter of the lens while unloaded.

2) Compressive force vs. compressive displacement.

3) Anterior displacement vs. compressive displacement.

The lenses evaluated and their abbreviations are listed below.

1)	Cilco SAC	(SAC5)
2)	Cilco MT (Symmetrical Multiflex)	(MT-5)
3)	IOLAB 91-Z (Azar)	(91-Z)
4)	Surgidev Leiske	(S-10)
5)	AMO Omnifit	(AC-21)

The complete set of data has already been reported to Cilco under separate cover and will be covered only in summary in this report.

Experimental

The procedure was to measure the three types of physical parameters before and after compressive fatigue of 0, 10^3, 10^4 and 10^5 cycles. The high cycle fatigue apparatus used to provide the repetitive cycling is shown in Figure 1. A gang sample fixture capable of holding five lenses at once was fabricated. As shown in Figure 2, it consists of five circular "football" shaped impressions milled into an aluminum block. The impressions have an effective diameter of 12.7 mm. The effective distance between the deepest points of the impressions was varied from 13.0 mm. to 11.5 mm. This was the closest approximation available to changing the overall diameter of the lenses from 13.0 mm to 11.5 mm. Allowances were made for the cross-sectional diameter of the loops; since they did not fit completely into the 90^o corner of the impression. Before any cycling the lenses were soaked in water for 24 hours so that any swelling associated with water uptake might occur. It was not known whether this time was sufficient for complete absorption. It was, however, the longest practical time. The lenses were immersed in water during the cycling and at all other times during testing except when the physical property measurements were being made. The repetitive cycling was performed simultaneously on five lenses of each type at 1.00 $\pm$ .05 Hz.

After each cycling period the lenses were allowed to relax approximately three hours before measurements were made. The measurements on all five lenses took about two hours at each stage. Assuming that the relaxation was exponential (many relaxation and creep phenomena are to a good approximation) the percentage of relaxation of all lenses within a group would be within 20% of each other.

At each stage of the cycling the overall unloaded dimension of the lenses were measured using a traveling microscope. The accuracy of the microscope is $\pm$ .001 mm; however because of the

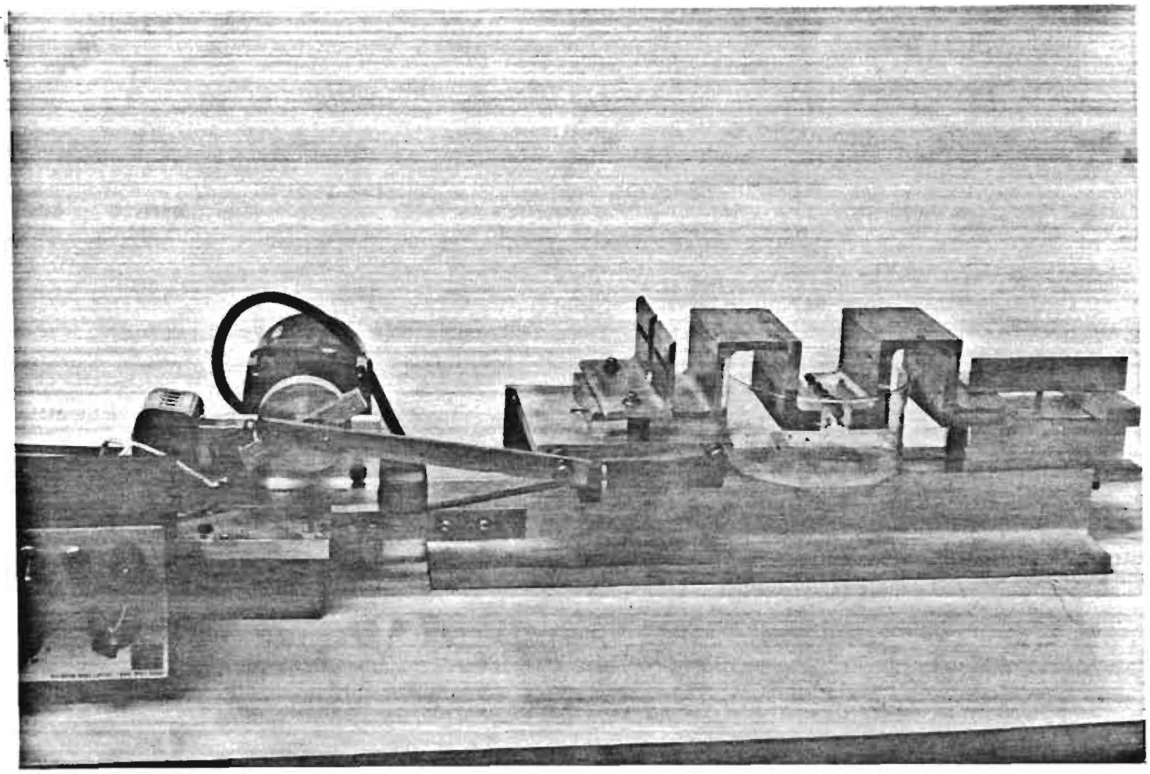

Figure 1. High Cycle Fatigue Apparatus

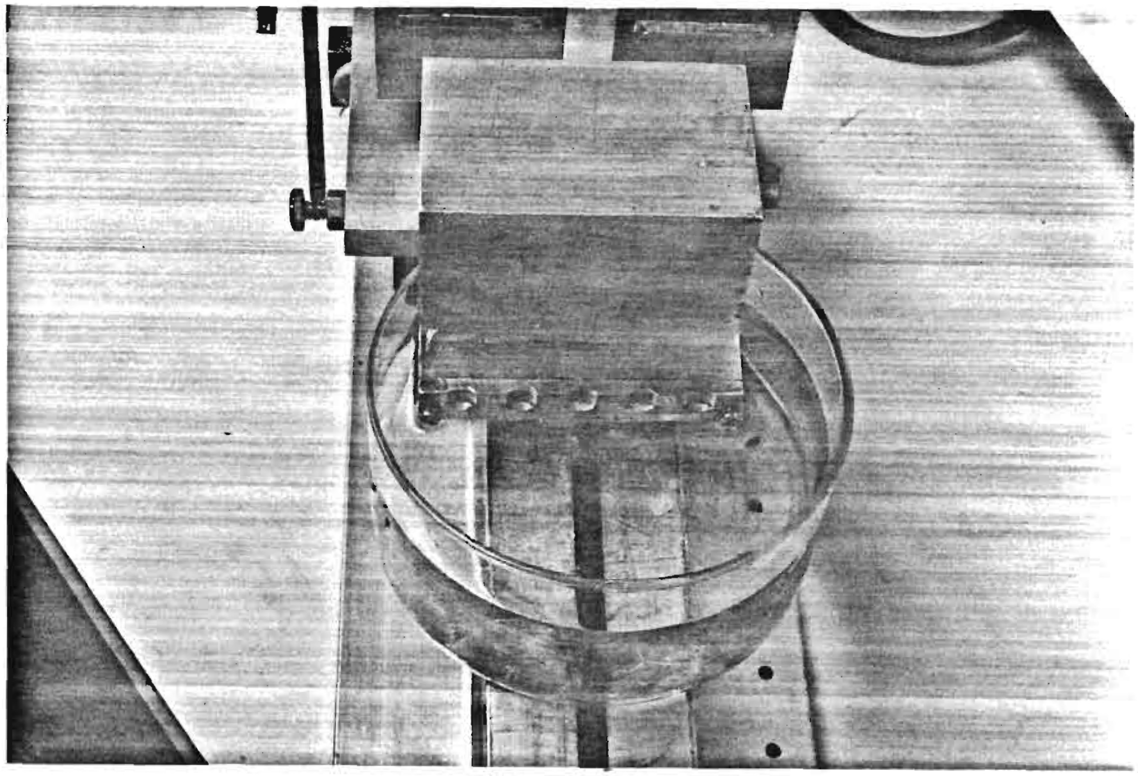

Figure 2. Multiple Sample Holding Fixture

radius of the lens loops, the water film adhering to their surface and the possible loop displacement during placement on the surface during measurement, the total accuracy of this measurement is about ± 0.01 mm. This measurement was made between the two points that were furtherest apart on each lens. On some styles this does not exactly correspond to the effective diameter because of the asymmetrical shapes; however it is a valid measurement for comparison of lenses of the same type. Table I gives a summary of this data.

At each stage of the fatigue cycling a compressive force vs. compressive displacement curve was measured using the microtensile device shown in Figure 3. The compressive displacement was cycled from the relaxed lens diameter to 11.0 mm. The forces were measured over one complete cycle (compression and relaxation) in which the displacement was varied at approximately 0.010 ± .0005 mm/sec. The lenses were measured one at a time in a sample holder of similar impression to that of the fatigue device. Table II gives a summary of the compressive force at maximum compression.

During a compression cycle the anterior displacement was measured employing the same traveling microscope (also ± 0.01 mm accuracy) which was used for the lens diameter measurements. A small particle of S_iO_2 (silica sand) was placed on the outer surface of the lens so that a sharp edge on which to focus the microscope would be present. This displacement was measured in increments of 0.5 mm of the compressive displacement from the maximum diameter down to 11.0 mm. Table III gives a summary of the anterior displacement.

Table I

WET DIAMETERS IN MM (MEASURED WITH TRAVELING MICROSCOPE)

Sample Type	Cycles	#1	#2	#3	#4	#5	$\overline{X}^*$	σ^*
	10^0	13.60	-----	13.59	13.59	13.60	13.595	0.005
SAC5	10^3	13.55	-----	13.53	13.54	13.54	13.54	0.007
	10^4	13.51	-----	13.56	13.52	13.55	13.535	0.021
	10^0	13.44	13.46	13.40	13.49	13.44	13.45	0.030
MT-5	10^3	13.40	13.47	13.41	13.44	13.34	13.41	0.044
	10^4	13.38	13.45	13.44	13.45	13.41	13.43	0.028
	10^5	13.28	13.30	13.27	13.30	13.28	13.29	0.013
	10^0	13.46	12.92	12.74	12.81	13.35	**	**
91-Z	10^3	13.38	12.86	12.78	12.80	13.22	**	**
	10^4	13.29	12.76	12.72	12.80	13.23	**	**
	10^5	13.15	12.71	12.54	12.66	13.01	**	**
	10^0	12.34	12.53	12.58	12.96^t	12.44	12.47	0.092
S-10	10^3	12.26	12.50	12.58	12.92^t	12.44	12.445	0.118
	10^4	12.24	12.49	12.59	12.86^t	12.44	12.44	0.127
	10^5	12.20	12.33	12.51	12.76^t	12.37	12.35	0.111

Table I (Continued)

	10^0	13.50	13.61	13.57	13.63	13.59	13.58	0.045
AC-21	10^3	13.52	13.57	13.59	13.62	13.52	13.56	0.039
	10^4	13.45	13.47	13.47	13.56	13.50	13.49	0.038
	10^5	13.35	13.43	13.38	13.37	13.40	13.39	0.028

**, $\bar{X}$ and σ have no meaning because of the difference in initial lens diameters, † lens #4 not included in $\bar{X}$ and σ because of different diameter.

$$*\bar{X} = \sum_i X_i/N = \text{AVERAGE}; \quad \sigma = \sqrt{\sum_i (X_i - \bar{X})^2/N} = \text{STD DEVIATION}$$

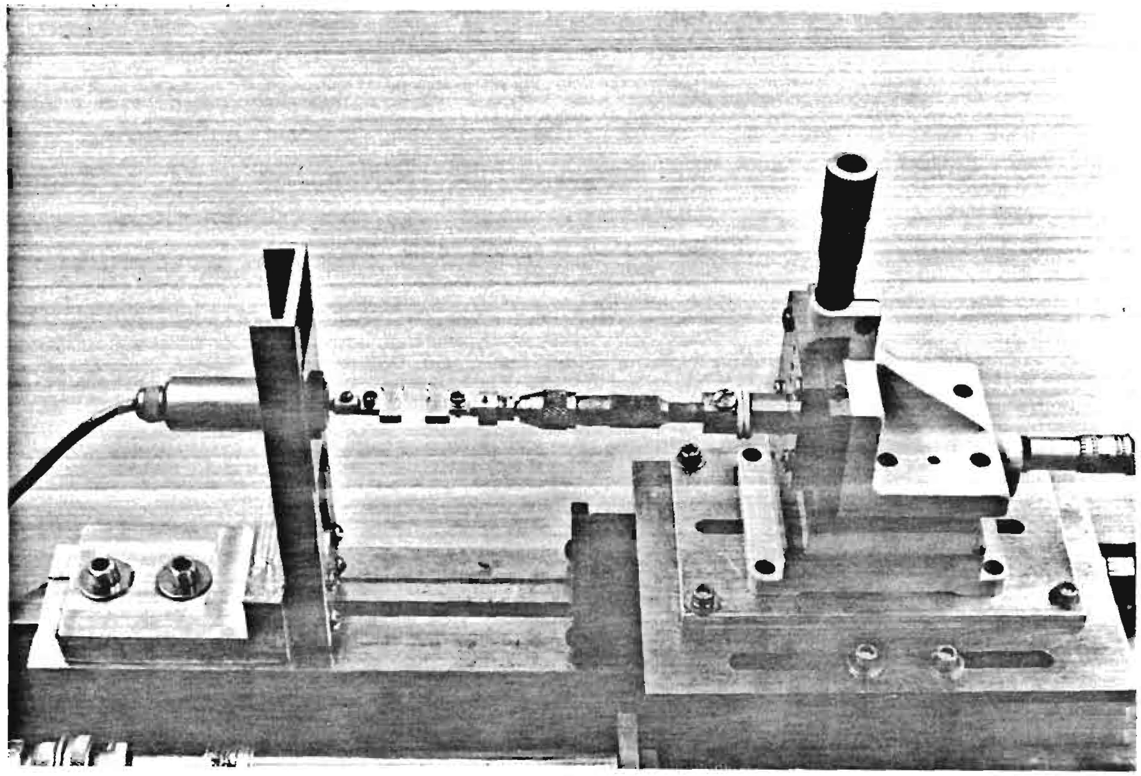

Figure 3. Microtensile Device Used in Compressive Force vs. Compressive Displacement Measurements

Table II

FORCE IN GRAMS AT 11.00 MM EFFECTIVE DIAMETER UNDER COMPRESSION

SAMPLE NUMBER

Sample Type	Cycles	#1	#2	#3	#4	#5	$\bar{X}$	σ
	10^0	1.10	-----	1.415	1.375	1.43	1.33	0.134
SAC5	10^3	1.165	-----	1.345	1.40	1.465	1.344	0.112
	10^4	1.045	-----	1.34	1.325	1.47	1.295	0.155
	10^5	1.145	-----	1.425	1.39	1.43	1.348	0.118
	10^0	4.44	4.43	5.12	7.50	5.10	5.318	1.28
MT-5	10^3	4.57	4.45	5.20	7.50	5.125	5.369	1.22
	10^4	4.425	4.425	5.125	7.51	5.10	5.317	1.30
	10^5	4.37	4.22	4.825	6.87	5.065	5.07	0.90
	10^0	6.69	6.24	5.69	7.00	5.89	**	**
91-Z	10^3	6.35	6.37	5.44	7.00	5.76	**	**
	10^4	6.14	5.61	5.23	6.55	5.38	**	**
	10^5	6.03	5.73	5.12	6.70	4.61	**	**
	10^0	13.46	15.36	12.30	14.41^t	14.77	13.97	1.19
S-10	10^3	14.07	15.33	12.21	13.91^t	14.75	14.09	1.17
	10^4	14.55	14.60	11.82	13.98^t	14.38	13.84	1.17
	10^5	14.70	14.96	12.20	13.35^t	17.10	14.74	1.74

Table II (Continued)

	10^0	4.45	4.40	4.40	5.82	5.14	4.84	0.56
AC-21	10^3	4.34	4.38	4.21	5.31	4.84	4.62	0.41
	10^4	4.08	4.07	4.12	4.91	4.56	4.35	0.34
	10^5	4.12	3.64	3.80	4.66	4.71	4.19	0.44

**, $\bar{X}$ and σ have no meaning because of difference in initial lens diameter

t not included in $\bar{X}$ and σ because of different initial diameter.

TABLE III

Anterior Displacement in MM at 11.00 MM Effective Diameter Under Compression

SAMPLE NUMBER

Sample Type	Cycle	#1	#2	#3	#4	#5	$\bar{X}$	σ
	10^0	0.29	----	0.26	0.29	0.32	0.29	0.021
SAC5	10^3	0.23	----	0.26	0.30	0.27	0.265	0.025
	10^4	0.20	----	0.20	0.27	0.25	0.23	0.31
	10^5	0.19	----	0.17	0.25	0.24	0.21	0.034
	10^0	0.55	0.38	0.49	0.44	0.63	0.50	0.087
MT-5	10^3	0.37	0.48	0.45	0.58	0.61	0.50	0.088
	10^4	0.45	0.52	0.45	0.46	0.55	0.485	0.041
	10^5	0.42	0.53	0.42	0.51	0.59	0.495	0.066
	10^0	2.22	2.06	2.09	2.12	2.27	**	**
91-Z	10^3	2.13	2.08	1.77	1.82	2.08	**	**
	10^4	1.95	1.98	1.70	1.72	1.93	**	**
	10^5	1.80	1.69	1.47	1.55	1.73	**	**
	10^0	1.38	1.56	1.64	1.86^t	1.49	1.52	0.096
S-10	10^3	1.39	1.48	1.57	1.81^t	1.45	1.47	0.065
	10^4	1.20	1.31	1.40	1.55^t	1.28	1.30	0.072
	10^5	1.21	1.25	1.38	1.34^t	1.19	1.26	0.074

Table III (Continued)

	10^0	0.34	0.17	0.27	0.14	0.25	0.235	0.072
AC-21	10^3	0.10	0.10	0.36	0.31	0.23	0.22	0.106
	10^4	0.07	0.28	0.45	0.22	0.15	0.235	0.129
	10^5	0.11	0.00	0.37	0.29	0.32	0.22	0.140

** $\overline{X}$ and σ have no meaning because of differences in initial lens diameters.
t not included in $\overline{X}$ and σ because of different initil lens diameter.

Discussion

Detailed oral discussions of these results were presented to Mr. Dan Winfield during his visit to Georgia Tech and will therefore be mentioned here in summary only. It is important at this point to note that the interpretation of these results is extremely subjective and should be done aided with a knowledge of the geometry of the lenses and the behavior materials involved. Care should be exercised when trying to compare lenses of different styles and perhaps even two different lenses of the same style. In addition, because of the complex nature of the phenomena, measured comparison of one particular point on a curve for one sample to the same point for another sample should be accompanied by the whole curves so that the relationships can be appropriately weighted as to "real" significance.

The only measurement that was consistent throughout the entire group was that of effective diameters of the lenses while unloaded. As can be seen from Table I. All groups showed a permanent deformation in the form of a 1% to 2% average reduction in effective diameter after 10^5 cycles. Thee reductions were limited to a maximum of 3%.

The compressive force and anterior displacement showed different characters for each type of lens. Figure 4 shows a typical compressive force vs. compressive displacement curve. The small vertical jumps are believed to be due to a rotation of the lenses in the holder which is exhibited as a frictional stick-slip phenomenan. Figure 5 shows the same lens with a significant amount of sticking. The sample holders were polished with #600 grit paper to reduce the sticking to a minimum.

The MT-5 samples showed no change in the general character of the curves during the cycling. There was a slight work hardening during the first few thousand cycles followed by a slight weakening with cycling up to 10^5 cycles. There was no significant change in anterior displacement. The SAC5 samples

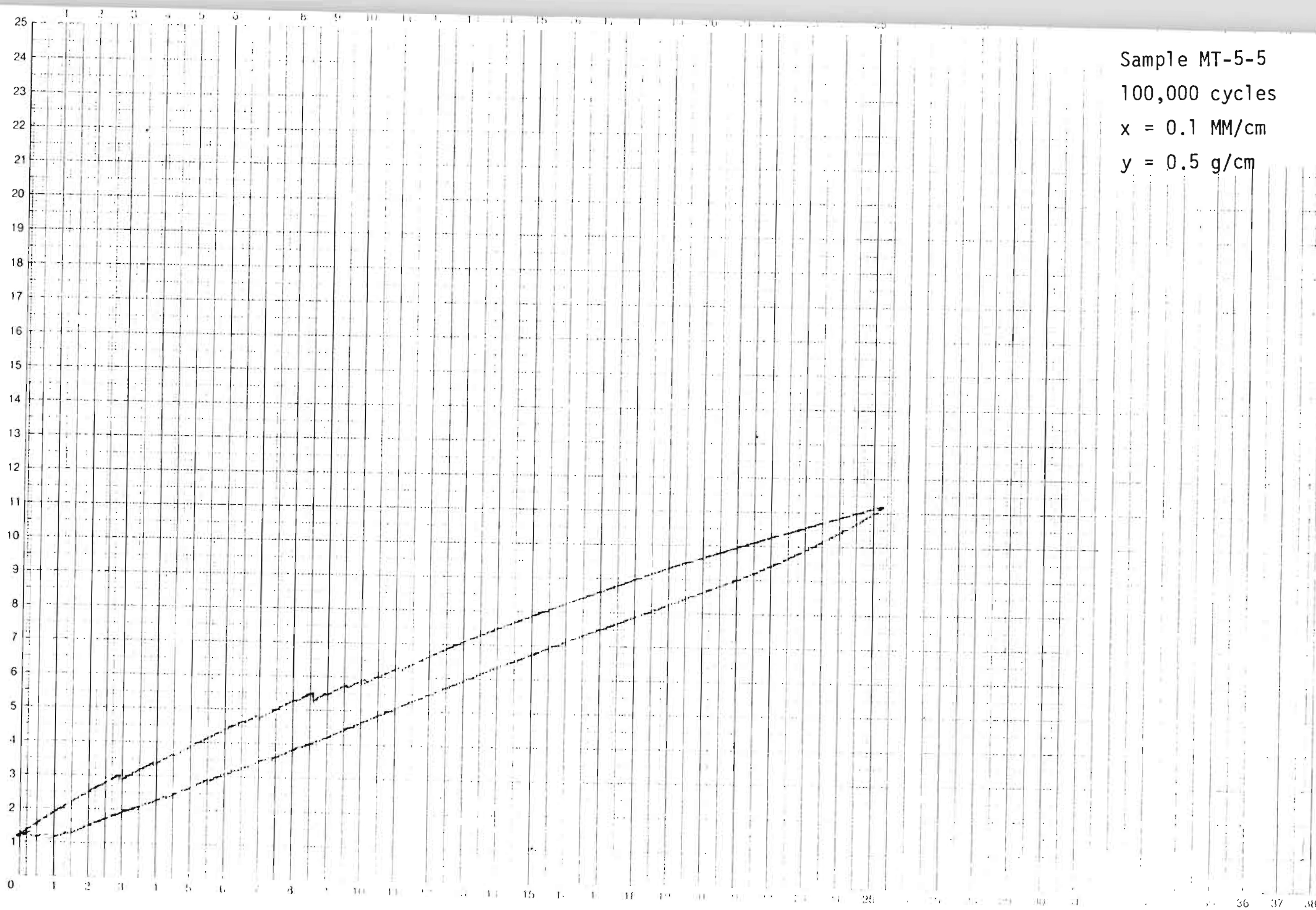

Figure 4. Force vs. Displacement Curve for Sample MT-5#5 After 10^5 Cycles

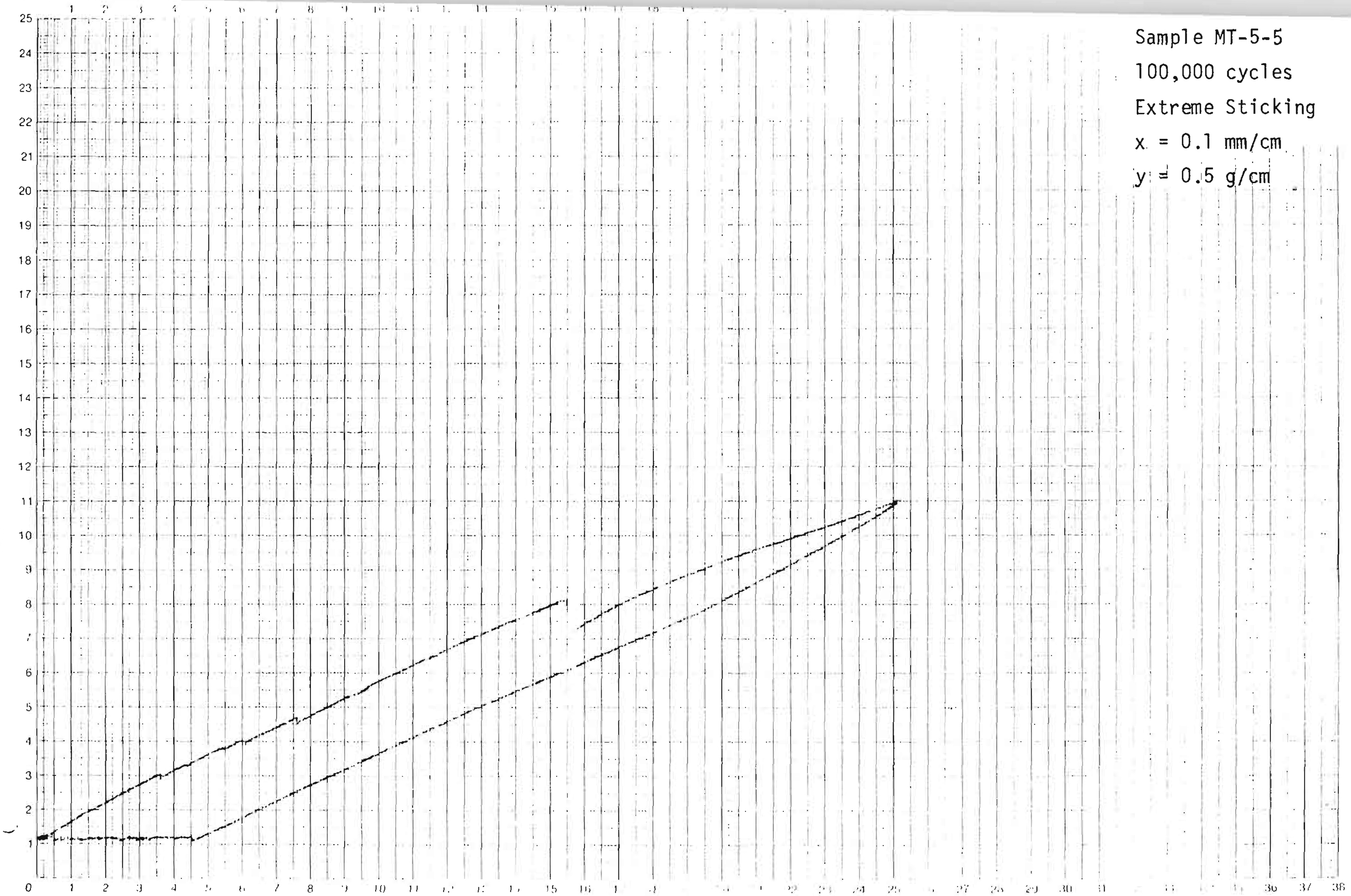

Figure 5. Force vs. Displacement Curve for the Same Sample and Same Fatigue Conditions as in Figure 4 but with Extreme Sticking

(typical example Figure 6) showed very little changes in character during cycling. Some samples showed a slight work hardening at some points and others showed a slight weakening. In contrast to the MT-5 samples there was an average reduction of about 30% in the maximum anterior displacement.

The 91-Z lenses show the most significant change in compressive force at 11.0 mm during the cycling. A reduction averaging 10% had occurred after 10^5 cycles. This was accompanied by a reduction in the hysteresis energy (area inside the curves). See Figures 7 and 8. There was also a 15% to 30% reduction in the anterior displacement at maximum deflection.

The force vs. displacement curves for both the 91-Z and S-10 type lenses are complex in nature. This is due to their closed loop construction. Under compression the loops first gave by compression in the plane of the lens then by vaulting. During vaulting one loop deflected more than the other creating an asymmetric system.

The S-10 style of lenses behaved in a manner similar to that of the 91-Z when compressed. They also showed a significant reduction of hysteresis energy (Figures 9 & 10) and an average of 20% reduction in anterior displacement after 10^5 cycles. They did not show the corresponding reduction in force at maximum compression. This force changed only slightly in these samples, sometimes showing a small increase and sometimes a small decrease.

The last style of lenses tested was the AC-21 which was an open loop type as the SAC5 and MT-5. These lenses showed simpler compressive force vs. displacement curves as did the other open loop lenses (Figure 11). These lenses showed little change in character during the cycling. They exhibited an average 15% to 10% reduction in force at maximum deflection and sporatic changes in anterior displacement at maximum deflection. This behavior of the anterior displacement was a function of the non-monotonic

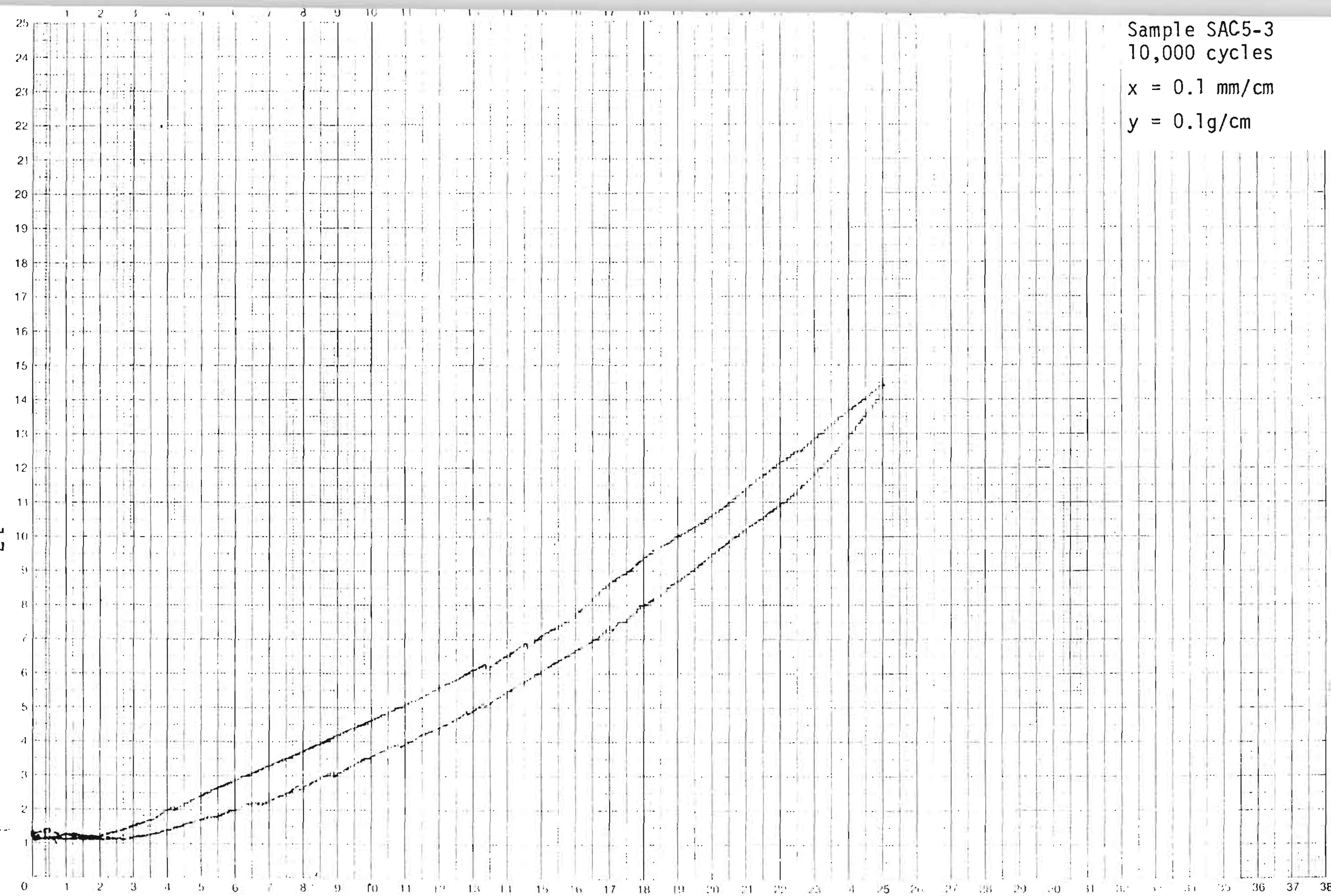

Figure 6. SAC5 #3 After 10^4 Cycles

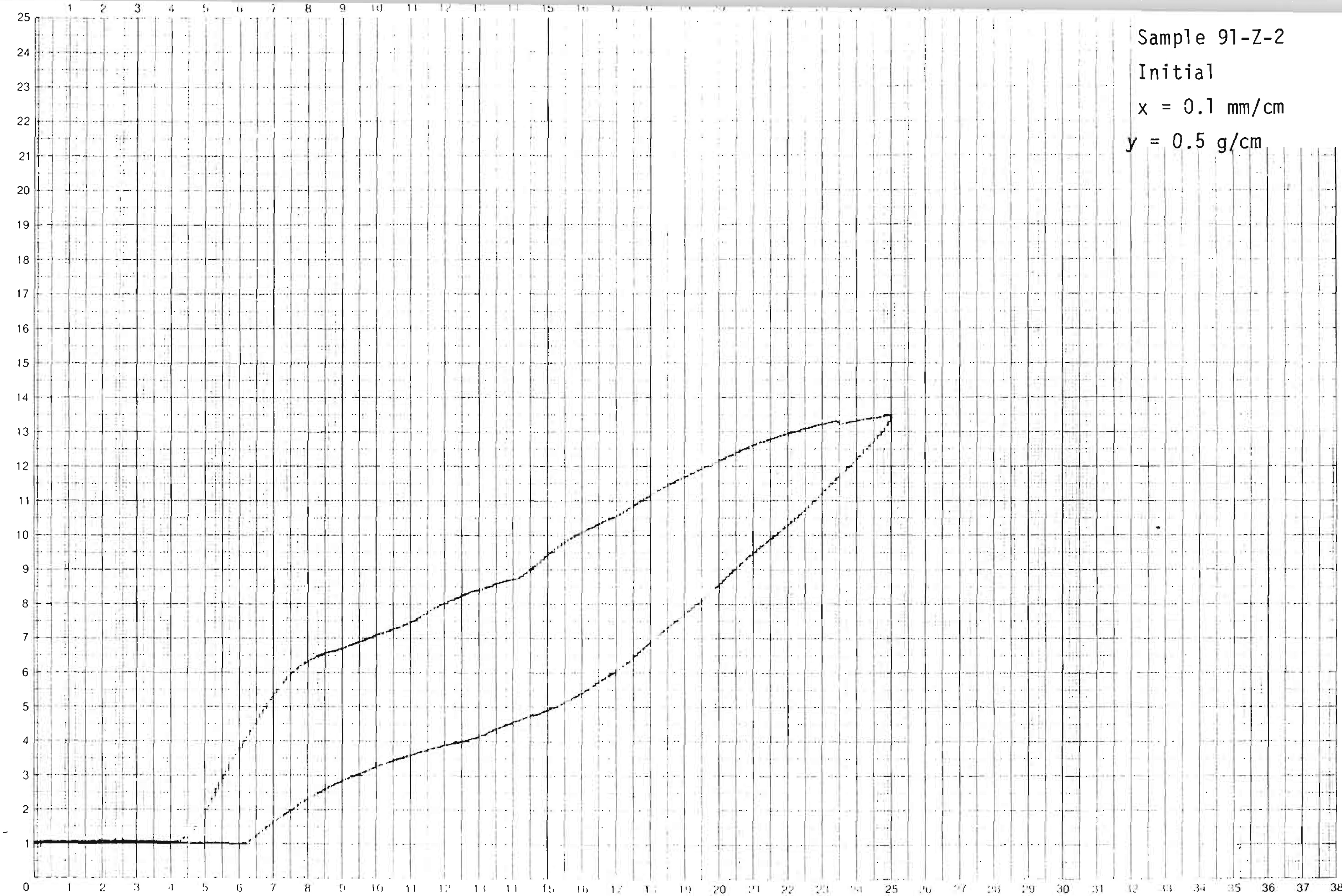

Figure 7. 91-Z-#2 Initial

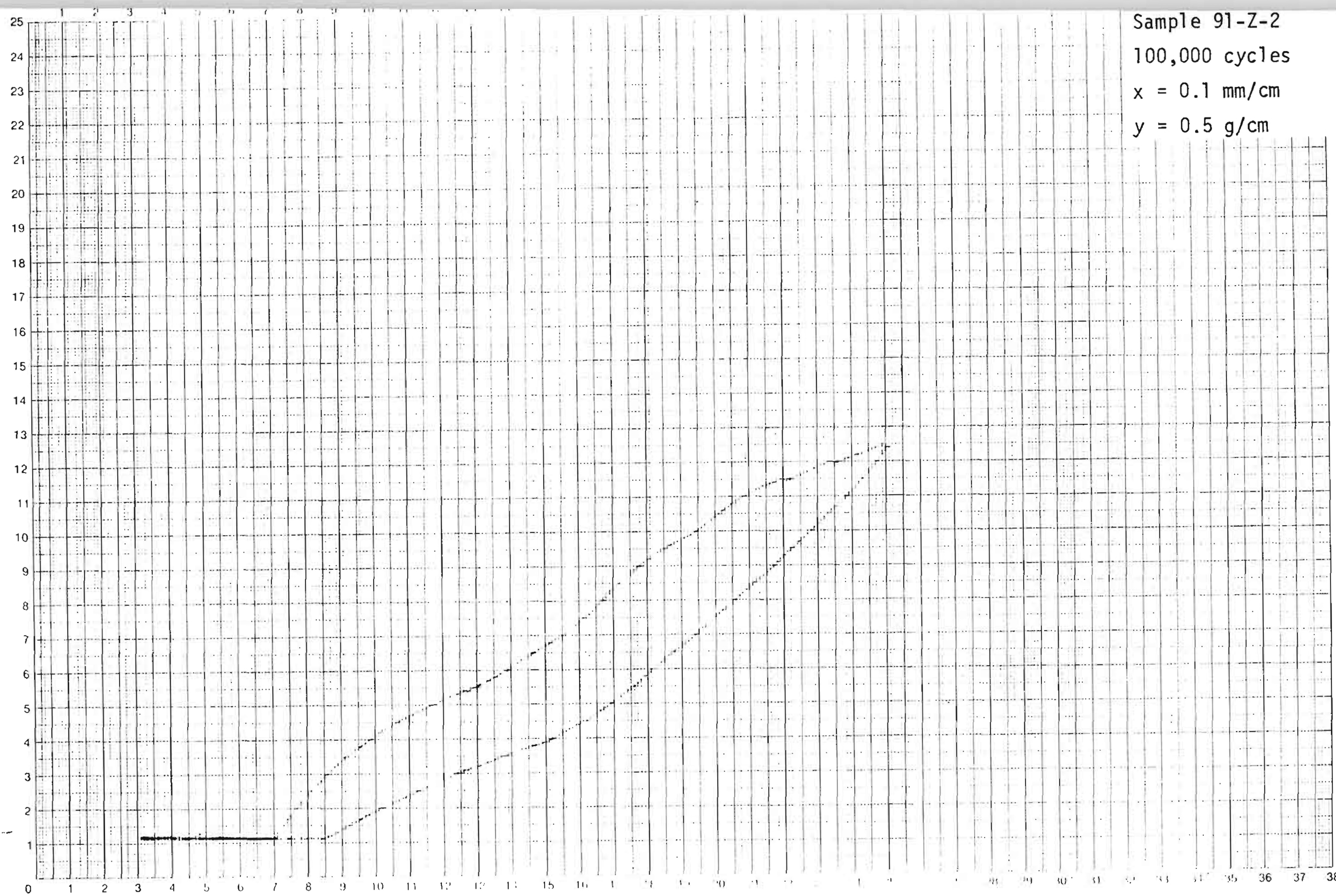

Figure 8. 91-Z-2 After 10^5 Cycles

Figure 9. S-10#2 Initial

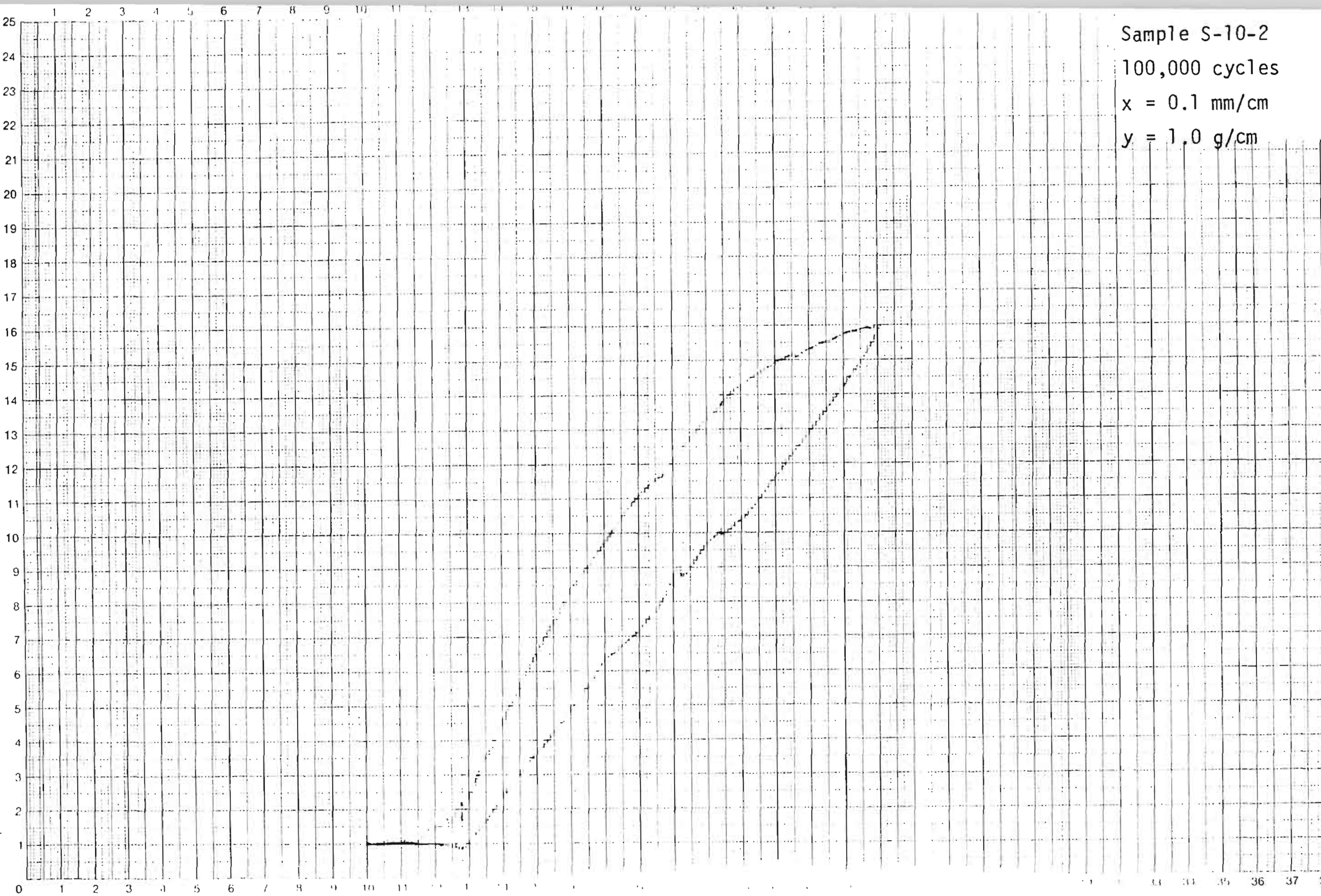

Figure 10. S-10#2 After 10^5 Cycles

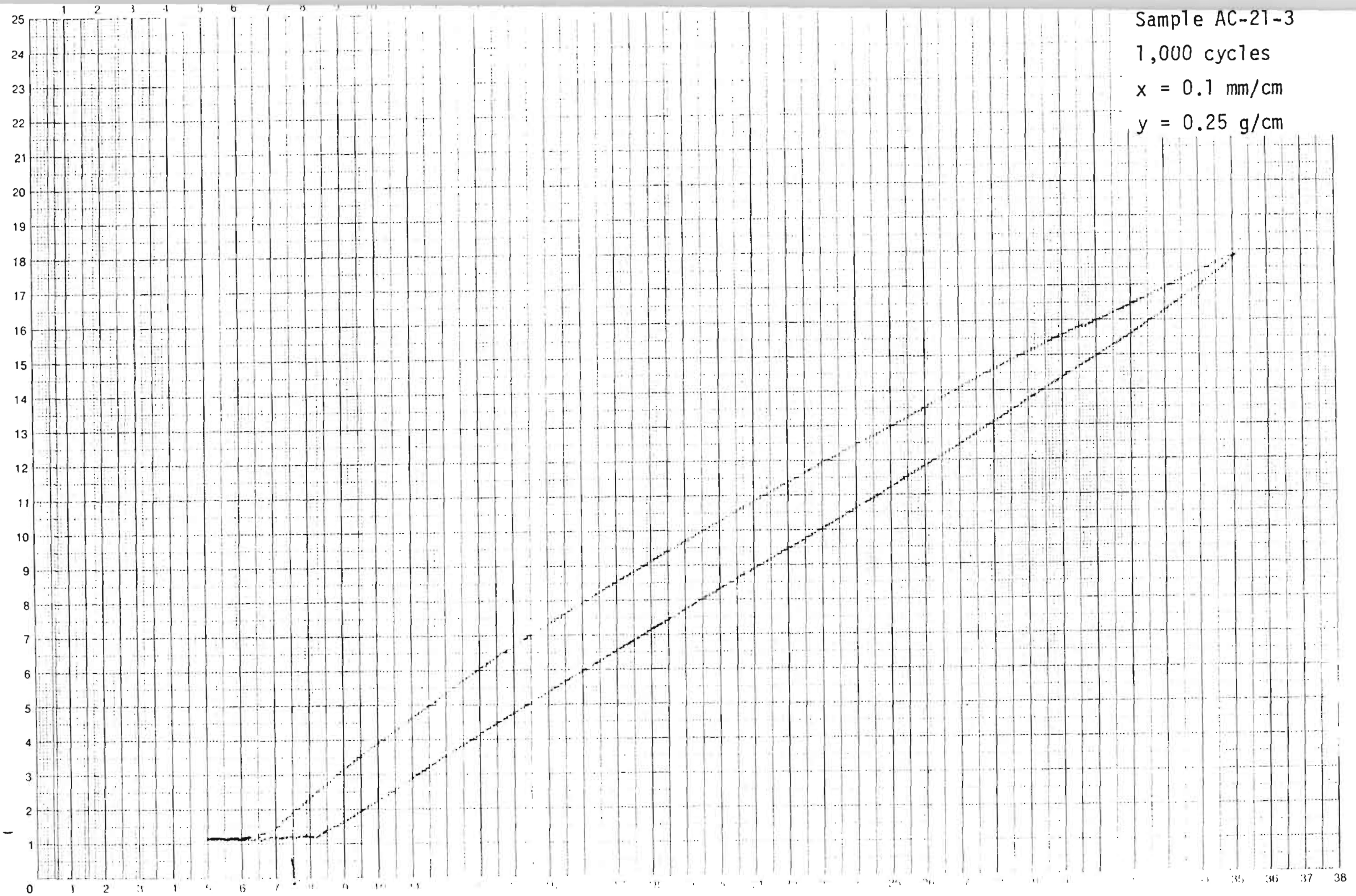

Figure 11. AC-21#3 After 10^3 Cycles

nature displayed. During compression the lenses showed a sharp negative anterior displacement change followed by a more gradual increase which ultimately went positive in most cases. This behavior emphasizes the fact that one must carefully consider the nature of the curves when trying to interpret single point data.

The complex character of the lenses and the data generated indicate that placing a large amount of effort in test and test equipment design is necessarily an important consideration in evaluating the behavior of these types of lenses and other complex systems. It would probably be beneficial to evaluate the materials first using more "standard" samples and then to proceed in testing the loop behavior later. Experiments should also be designed to separately test different parts of the loop eg: the joint between the loop and lens. After these tests the lenses can be evaluated as a unit with a much greater understanding of their behavior.